

Please type a plus sign (+) inside this box

OCT 05 2001

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 4

Complete if Known

| | |
|------------------------|-------------------|
| Application Number | 09/709,774 |
| Filing Date | November 8, 2000 |
| First Named Inventor | Sette, Alessandro |
| Group Art Unit | 1645-1644 |
| Examiner Name | Not Assigned |
| Attorney Docket Number | 018623-006240US |

RECEIVED
TECH CENTER 1600
OCT 9 2001

U.S. PATENT DOCUMENTS

| Examiner Initials* | Cite No. ¹ | U.S. Patent Document | | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|--------------------|-----------------------|----------------------|--------------------------------------|---|---|--|
| | | Number | Kind Code ² (if known) | | | |
| AJ | 1 | 5,114,713 | | Sinigaglia | 05/19/92 | — |
| | 2 | 5,196,512 | | Bianchi, et al. | 03/23/93 | — |
| | 3 | 5,336,758 | | Berzofsky, et al. | 08/09/94 | — |
| | 4 | 5,679,640 | | Gaeta, et al. | 10/21/97 | — |
| | 5 | 5,736,142 | | Sette, et al. | 04/07/98 | — |
| | 6 | 5,785,973 | | Bixler, et al. | 07/28/98 | — |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

FOREIGN PATENT DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | | | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T ⁶ |
|--------------------|-----------------------|-------------------------|---------------------|--------------------------------------|---|---|--|----------------|
| | | Office ³ | Number ⁴ | Kind Code ⁵ (if known) | | | | |
| AJ | 7 | EPO | 0 534 615 A2 | | Vitiello, et al. | 03/31/93 | — | |
| | 8 | WIPO | WO 92/02543 | | Gaeta, et al. | 02/20/92 | — | |
| | 9 | WIPO | WO 93/05011 | | Cottens, et al. | 03/18/93 | — | |
| | 10 | WIPO | WO 94/20127 | | Grey, et al. | 09/15/94 | — | |
| | 11 | WIPO | WO 95/07707 | | Sette, et al. | 03/23/95 | — | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |

| | | | |
|--------------------|-----------|-----------------|---------|
| Examiner Signature | <i>AJ</i> | Date Considered | 3-23-03 |
|--------------------|-----------|-----------------|---------|

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

SF 1274995 v1

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449B/PTO

INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet

2

of

4

Complete if Known

| | |
|----------------------|-------------------|
| Application Number | 09/709,774 |
| Filing Date | November 8, 2000 |
| First Named Inventor | Sette, Alessandro |
| Group Art Unit | 1645 / 644 |
| Examiner Name | Not Assigned |

Attorney Docket Number 018623-006240US

RECEIVED
OCT 09 2001
TECH CENTER 600/2900
U.S. PATENT & TRADEMARK OFFICE

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

| Examiner Initials * | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
|---------------------|-----------------------|---|----------------|
| AS | 12 | ALEXANDER, et al., "Development of High Potency Universal DR-Restricted Helper Epitopes by Modification of High Affinity DR-Blocking Peptides"; <i>Immunity</i> Vol. 1, 751-761 (Dec. 1994) | |
| | 13 | BARTOLONI, et al., "Immunogenicity of meningococcal B polysaccharide conjugated to tetanus toxoid or CRM197 via adipic acid dihydrazide"; <i>Vaccine</i> Vol. 13, No. 5, pp. 463-470 (1995) | |
| | 14 | BIXLER, et al., "Synthetic Peptide Representing a T-cell Epitope of CRM197 Substitutes as Carrier Molecule in a Haemophilus Influenzae Type B (Hib) Conjugate Vaccine"; <i>Adv. Exp. Med. Biol.</i> 251: 175-180, (1989) | |
| | 15 | BORRAS-CUESTA et al., "Engineering of Immunogenic Peptides by Co-Linear Synthesis of Determinants Recognized by B and T Cells," <i>Eur. J. Immunol.</i> Vol. 17:1213-1215 (1987) | |
| | 16 | BRETT et al., "Fine Specificity of T Cell Recognition of the Same Peptide in Association With Different I-A Molecules," <i>Journal of Immunology</i> , Vol. 143 No. 3 771-779 (Aug. 1989) | |
| | 17 | BROWN, et al., "Three-dimensional structure of the human class II histocompatibility antigen HLA-DR1"; <i>Nature</i> , Vol. 364, 33-39, (July 1993) | |
| | 18 | BUSCH, et al., "Degenerate binding of immunogenic peptides to HLA-DR proteins on B cell surfaces"; <i>International Immunology</i> , Vol. 2, No. 5 443-451 (1990) | |
| | 19 | CHONG, et al., "A Strategy for Rational Design of Fully Synthetic Glycopeptide Conjugate Vaccines"; <i>Infection and Immunity</i> , Vol. 65, No. 12 4918-4925, (December 1997) | |
| | 20 | CHU, et al., "Further Studies on the Immunogenicity of Haemophilus influenzae Type b and Pneumococcal Type 6A Polysaccharide-Protein Conjugates"; <i>Infection and Immunity</i> , Vol. 40, No. 1, 245-256 (April, 1983) | |
| | 21 | CLARKE et al., "Improved Immunogenicity of a Peptide Epitope After Fusion to Hepatitis B Core Protein," <i>Nature</i> , Vol. 330, 381-384 (November 1987) | |
| | 22 | DiGeorge et al., "Immune Responses of Seven Different 'Promiscuous' T-Cell Epitopes on Chimeric Peptide Vaccine Design," <i>Peptide Vaccines and Immunology</i> , pp 732-733, The Ohio State University, Columbus, OH 43210 | |
| | 23 | FERN et al., "Promiscuous Malaria Peptide Epitope Stimulates CD45Ra T Cells From Peripheral Blood of Nonexposed Donors," <i>Journal of Immunology</i> , Vol. 148:907-913 (1992) | |
| | 24 | FERRARI et al., "Identification of Immunodominant T Cell Epitopes of the Hepatitis B Virus Nucleocapsid Antigen," <i>J. Clin. Invest.</i> Vol. 88:214-222 pp. 168-170 (July 1991) | |
| | 25 | FRANCIS et al., "Non-Responsiveness to a Foot-and-Mouth Disease Virus Peptide Overcome by Addition of Foreign Helper T-Cell Determinants," <i>Nature</i> , Vol. 330 (Nov. 1987) | |
| | 26 | FRANKE, et al., "Pan DR binding sequence provides T-cell help for induction of protective antibodies against Plasmodium yoelii sporozoites"; <i>Vaccine</i> , 17: 1201-1205 (1999) | |

Examiner Signature

Ann DeLune

Date Considered

3-23-03

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

SF 1274995 v1

Please type a plus sign (+) inside this box



PTO/SB/08B (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet

3

of

4

Complete if Known

| | |
|------------------------|-------------------|
| Application Number | 09/709,774 |
| Filing Date | November 8, 2000 |
| First Named Inventor | Sette, Alessandro |
| Group Art Unit | 1645-1644 |
| Examiner Name | Not Assigned |
| Attorney Docket Number | 018623-006240US |

TECH CENTER 1600
OCT 9 2001
16002000

| OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS | | |
|--|-----------------------|--|
| Examiner Initials * | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. |
| M | 27 | GREENSTEIN et al., "A Universal T Cell Epitope-Containing Peptide From Hepatitis B Surface Antigen Can Enhance Antibody Specific for HIV pp120," <i>Journal of Immunology</i> Vol. 148:3970-3977 No. 12 (June 1992) |
| | 28 | HERVAS-STUBBS, et al. "Overcoming class II-linked non-responsiveness to hepatitis B vaccine"; <i>Vaccine</i> Vol. 12, No. 10, (1994) pp 867-871 |
| | 29 | HILL, et al., "Conformational and Structural characteristics of Peptides Binding to HLA-DR Molecules"; <i>The Journal of Immunology</i> , Vol. 147, No. 1, 189-197 (July 1991) |
| | 30 | HO et al., "Identification of Two Promiscuous T Cell Epitopes from Tetanus Toxin*," <i>Eur. J. Immunol.</i> Vol. 20:477-483 (1990) |
| | 31 | ISHIOKA, et al. "MHC Interaction and T Cell Recognition of Carbohydrates and Glycopeptides"; <i>The Journal of Immunology</i> Vol. 148 No. 8, pp. 2448-2451 (April 1992) |
| | 32 | ISHIOKA, et al. "Major histocompatibility complex class II association and induction of T cell responses by carbohydrates and glycopeptides"; <i>Springer Semin. Immunopathol.</i> 15:293-302 (1993) |
| | 33 | KAUMAYA et al., "Immunogenicity and Antigenicity of a Promiscuous T-Cell Epitope and a Topographic B-Cell Determinant of the Protein Antigen LDH-C4," <i>Peptides Chemistry and Biology, Proceedings of the Twelfth American Peptide Symposium</i> June 16-21, 1991, Cambridge, Massachusetts, pp883-885 |
| | 34 | KAUMAYA et al., "A Universal HTLV-I Template Vaccine Incorporating Cytotoxic, Neutralizing and Promiscuous Epitope," <i>Peptides, Vaccines and Immunology</i> , pp 712-714 The Ohio State University, Columbus, OH 43210. |
| | 35 | KRIEGER, et al., "Single Amino Acid Changes in DR and Antigen Define Residues Critical for Peptide-MHC Binding and T Cell Recognition"; <i>The Journal of Immunology</i> , Vol. 146, No. 7, 2331-2340 (April 1991) |
| | 36 | LETT, et al., "Immunogenicity of Polysaccharides Conjugated to Peptides Containing T- and B-cell Epitopes"; <i>Infection and Immunity</i> Vol. 62, No. 3, 785-792, (March 1994) |
| | 37 | MEISTER et al., "Two Novel T Cell Epitope Prediction Algorithms Based on MHC-Binding Motifs; Comparison of Predicted and Published Epitopes from Mycobacterium tuberculosis and HIV Protein Sequences," <i>Vaccine</i> Vol 13(6):581-591 (1995) |
| | 38 | MILICH et al., "Antibody Production to the Nucleocapsid and Envelope of the Hepatitis B Virus Primed by a Single Synthetic T Cell Site" <i>Nature</i> Vol. 329 pp. 547-549(Oct 1987) |
| | 39 | O'SULLIVAN et al., "Characterization of the Specificity of Peptide Binding To Four DR Haplotypes," <i>Journal of Immunology</i> Vol. 145:1799-1808 (Sept 1990) |
| | 40 | O'SULLIVAN, et al., "Truncation Analysis of Several DR Binding Epitopes"; <i>The Journal of Immunology</i> , Vol. 146, No. 4, 1240-1246 (February 1991) |
| ✓ | 41 | O'SULLIVAN et al., "On the Interaction of Promiscuous Antigenic Peptides with Different DR Alleles," <i>Journal of Immunology</i> Vol. 147:2663-2669 (Oct. 1991) |

| | | | |
|--------------------|--------------------|-----------------|---------|
| Examiner Signature | <i>Am. S. Chen</i> | Date Considered | 3-23-01 |
|--------------------|--------------------|-----------------|---------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

SF 1274995 v1

RECEIVED

Please type a plus sign (+) inside this box +

PTO/SB/08B (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| | | | |
|---|-----------------|--------------------------|--|
| Substitute for form 1449B/PTO | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | | |
| (use as many sheets as necessary) | | | |
| Sheet | 4 | | |
| of | 1 | | |
| Attorney Docket Number | 018623-006240US | | |
| TECH CENTER 1600/2900 OCT 05 2001 RECEIVED OCT 05 2001 U.S. PATENT AND TRADEMARK OFFICE | | | |

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

| Examiner Initials * | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
|---------------------|-----------------------|---|----------------|
| AM | 42 | PANINA-BORDIGNON, et al., "Universally immunogenic T cell epitopes: promiscuous binding to human MHC class II and promiscuous recognition by T cells"; Eur. J. Immunol. 19: 2237-2242 (1989) | |
| | 43 | PARTIDOS et al., "Prediction and Identification of a T Cell Epitope in the Fusion Protein of Measles Virus Immunodominant in Mice and Humans," Journal of General Virology Vol. 71:2099-2105 (1990) | |
| | 44 | POWELL, et al., "Peptide Stability in Drug Development. II. Effect of Single Amino Acid Substitution and Glycosylation on Peptide Reactivity in Human Serum"; Pharmaceutical Research, Vol. 10, No. 9, 1268-1273 (1993) | |
| | 45 | ROCHE, et al., "High-Affinity Binding of an Influenza Hemagglutinin-Derived Peptide to Purified HLA-DR"; The Journal of Immunology, Vol. 144, No. 5, 1849-1856 (March 1990) | |
| | 46 | SINIGAGLIA et al., "A Malaria T-Cell Epitope Recognized in Association with Most Mouse and Human MHC Class II Molecules," Nature Vol. 336:22/29 (Dec 1988) | |
| | 47 | SOUTHWOOD, et al., "Several Common HLA-DR Types Share Largely Overlapping Peptide Binding Repertoires", The Journal of Immunology, 160: 3363-3373 (1998) | |
| | 48 | STAGG et al., "Primary Human T-Cell Responses to the Major Outer Membrane Protein of Chlamydia trachomatis," Immunology Vol. 79:1-9 (1993) | |
| ✓ | 49 | WANG et al., "Directionality in 'promiscuous' T-Cell Epitope Selection on Colinear B- and T-Cell Constructs," Peptide Vaccines and Immunolgy, pp. 753-754, The Ohio State University, Columbus, OH 43210 | |
| | | | |

| | | | |
|--------------------|--------------------|-----------------|---------|
| Examiner Signature | <i>Am. de Eloy</i> | Date Considered | 3-23-03 |
|--------------------|--------------------|-----------------|---------|

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

SF 1274995 v1